

Atty Dkt. No.: CALD-007  
USSN: 10/029,407

### REMARKS

In view of the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 1-23, the only claims pending and currently under examination in this application.

#### Rejections Under 35 U.S.C. §102(b)

Claims 1-18 have been rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Meyer et al. (WO 93/17978).

According to the MPEP, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Additionally, the identical invention must be shown in as complete detail as is contained in the claim. See MPEP 2131.

The presently claimed invention is founded on the discovery by the inventors that the topical administration of an NSAID formulation is effective for ameliorating headache pains. Elements of the claimed invention include topically applying a NSAID formulation to a keratinized skin surface of the head wherein the NSAID is the only active agent present in the topical formulation. Accordingly, the rejected claims recite the limitation that an NSAID is the only active agent.

Meyer, on the other hand, is directed to administration mediums that include a first active agent and nitrous oxide. Nitrous oxide is a known active agent. Nitrous oxide has been shown to have potent analgesic activities in both animals and humans when administered topically or locally to tissues: See e.g.,

#### **1. Nitrous Oxide Revisited: Evidence for Potent Antihyperalgesic Properties.**

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**Richeb  P, Rivat C, Creton C, Laulin JP, Maurette P, Lemaire M, Simonnet G.**  
***Anesthesiology*. 2005 Oct;103(4):845-854.**

**2. Effect of nitrous oxide in reducing pain of propofol injection in adult patients.**  
**Sinha PK, Neema PK, Rathod RC.**  
***Anaesth Intensive Care*. 2005 Apr;33(2):235-8.**

Where the abstracts for these references are provided in Exhibit A to this response.

In maintaining the rejection, the Office asserts that the nitrous oxide set forth in Meyer is not an active agent.

However, as demonstrated by the above publications, nitrous oxide is a known active agent, despite its characterization in Meyer. The Office acknowledges that the nitrous oxide set forth in WO 93/17978 is an active agent that is used in a topical dermatological composition. The properties inherent within the nitrous oxide set forth in the '978 publication that make it an active agent do not disappear simply because the nitrous oxide is being used in a dermatological composition that now includes a NSAID. Meyer itself refers to the nitrous oxide as an "active drug potentiating adjuvant." See page 13, lines 9 – 18.

In addition, Claim 9 specifies that the topical formulation is a patch. Meyer fails to teach a patch formulation. Accordingly, Claim 9 is even further distinguished from Meyer.

Accordingly, Meyer does not teach a topical formulation having an NSAID as the only active agent as set forth in the subject claims, but rather teaches a composition that includes at least two active agents: (1) an NSAID, and (2) nitrous oxide. Therefore, the Applicants respectfully request the rejection of Claims 1-18 over Meyer be withdrawn.

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**Rejections Under 35 U.S.C. §103(a)**

Claims 19-23 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the disclosures of Meyer et al. (WO 93/17978).

According to the MPEP § 706.02 (j), to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

As described above, the presently claimed invention is directed to a topical formulation that includes an NSAID as the only active agent. Meyer on the other hand is directed to a composition that includes at least two active agents: (1) an NSAID, and (2) nitrous oxide. Accordingly, Meyer does not teach or suggest every element of the subject invention and, therefore, a *prima facie* case of obviousness has not been established. In view of the above, the Applicants respectfully request that this rejection be withdrawn.

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### CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number CALD-007.

Respectfully submitted,  
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Date: October 28, 2005

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Exhibit A

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